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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,340	02/16/2001	Ming-Hui Wei	CL000763	1842

25748 7590 06/03/2004

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/03/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/784,340

Applicant(s)

WEI ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,8,9 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,8,9 and 24-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: Alignment

**DETAILED ACTION**

***Status of the Application***

Claims 4, 8-9, 24-30 are pending.

*Ex parte* prosecution of the instant application is re-opened as new ground(s) of rejection and references relevant to the examination of the instant application are now available. An action on the merits follows.

***Priority***

1. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 119(e) to provisional application No. 60/228,893 filed on 08/30/2000.

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 4, 8-9, 24-30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 4, 8-9, 24-30 are directed to polynucleotides encoding a glucuronosyltransferase comprising SEQ ID NO: 2, host cells, vectors, and a method to recombinantly produce the polypeptide of SEQ ID NO: 2. While the specification asserts that the polypeptide of SEQ ID NO: 2 is a protein related to the UDP-glucuronosyltransferase family of proteins and it appears that the closest structural homologs are UDP-glucuronosyltransferases, the claimed invention lacks utility for the following reasons. This asserted utility is not specific as the specification fails to provide (1) substrates for the polypeptide of SEQ ID NO: 2, or (2) any information as to the type of UDP-glucuronosyltransferase the polypeptide of SEQ ID NO: 2 is. As known in the art and evidenced by Jin et al. (cited in previous Office Action Paper

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No. 8 mailed on 9/10/2001) UDP-glucuronosyltransferases are separated into two families based on their evolutionary divergence. Classification into a particular family also determines the type of compounds being glucuronidated (page 496, last paragraph, continuing on page 497). Therefore, in the absence of any information as to the type of UDP-glucuronosyltransferase or the substrates, the polypeptide of SEQ ID NO: 2 lacks a specific utility.

Furthermore, the asserted utility for the polypeptide of SEQ ID NO: 2 as a UDP-glucuronosyltransferase, particularly in view of a lack of knowledge as to its substrates or the family of UDP-glucuronosyltransferases to which it belongs, is not substantial since it will require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. See e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The instant situation is analogous to the lack of substantial utility examples provided by MPEP § 2107.01 in that basic research is required to study the properties of the claimed polynucleotides and the corresponding polypeptide as well as the mechanisms in which the claimed polynucleotides are involved. Since the instant specification does not disclose an specific and substantial "real world" use for the polypeptide of SEQ ID NO: 2, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

4. Claims 4, 8-9, 24-30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 4, 8-9, 24, 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Policky et al. (U.S. Publication No. 2004/0029125; corresponding 371 U.S. application is 10/258080) and Policky et al. (WO/ 01/79468 A2, PCT/US01/11869). Since the specification of both documents is the same, specific references will be made with respect to U.S. Publication No. 2004/0029125. Policky et al. discloses a polynucleotide (1636 nucleotides long) which encodes a polypeptide which is 100% sequence identical to the polypeptide of SEQ ID NO: 2 (Incyte ID 2434655CD1; Table 2, SEQ ID NO: 1 and 11). See attached alignment. Policky et al. also discloses expression vectors, such as plasmids, wherein the polynucleotide is operably linked to a promoter, host cells transformed with the expression vectors, and a process for recombinantly producing the polypeptide wherein the transformed host cells are cultured (paragraphs 253-264). Claims 4, 8-9, 24, 27-30 are directed to a polynucleotide encoding the polypeptide of SEQ ID NO: 2, expression vectors comprising said polynucleotide, host cells transformed with said expression vectors, and a process for producing the polypeptide of SEQ ID NO: 2 by culturing the transformed host cells. Therefore, the teachings of Policky et al. anticipate the claims as written.
6. It has been determined that the polypeptide of SEQ ID NO: 1 and the polynucleotide of SEQ ID NO: 11 in U.S. Publication No. 2004/0029125 and WO/ 01/79468 A2 were first disclosed in U.S. provisional Application No. 60/197590 filed on 4/13/2000. Since priority has been claimed to U.S. provisional Application No. 60/197590 filed on 4/13/2000, the 102(e) date for U.S. Publication No. 2004/0029125 and WO/ 01/79468 A2 is 4/13/2000.

*Art of Interest*

7. It is noted that U.S. Publication No. 20040029221 (Baker et al.) , which corresponds to U.S. Application No. 10/206915, discloses a polypeptide ( SEQ ID NO: 522) 100% sequence identical to the polypeptide of SEQ ID NO: 2 of the instant application as well as a polynucleotide encoding said polypeptide ( SEQ ID NO: 521). U.S. Application No. 10/206915 claims priority to provisional application 60/209832 filed on 6/5/2000. At this time, the priority claim to provisional application 60/209832 has not been verified. If it is later verified that SEQ ID NO: 521-522 were first disclosed in provisional application 60/209832, claims 4, 8-9, 24, 27-30 will be rejected under 35 U.S.C. 102(e) as being anticipated by Baker et al. This will not be considered as new ground(s) of rejection.

*Conclusion*

8. No claim is in condition for allowance.
9. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.
10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.  
Patent Examiner  
Art Unit 1652

DR  
May 28, 2004

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